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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,650	07/07/2003	Yong Hua Zhu	LOMAU.122C1	7638

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EXAMINER

HAND, MELANIE JO

ART UNIT	PAPER NUMBER
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3761

NOTIFICATION DATE	DELIVERY MODE
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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/614,650	Applicant(s) ZHU ET AL.	
	Examiner MELANIE J. HAND	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-4,6,8-15,17-22 and 24-41 is/are pending in the application.
- 4a) Of the above claim(s) 2-4,6,8,9,11-15,17-20 and 25-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10,21,22,24,34-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed May 15, 2009 have been fully considered but they are not persuasive. Applicant's sole argument appears to be that examiner's has interpreted the word "permanently" in an unreasonable manner and thus the prior art of Nash, in light of this interpretation, does not anticipate or render unpatentable the claimed invention. While applicant intends to rely on a dictionary definition, even the dictionary definition implies a certain time interval that the definition is based on, i.e. infinite time. This can not be applied to applicant's invention because it is clear, in the examiner's opinion, that the claimed device is created and assembled from more than one part prior to use. Therefore, the first and second distal openings recite in the claims cannot be considered to be permanently maintained at any position relative to one another if they do not exist for an infinite time period. Contrary to applicant's assertion, examiner applied a very reasonable interpretation of "permanently", given the lack of any definition of the term in the specification, i.e. that the time period implicit in "permanently maintained" is the time interval the device is being used. As applicant has presented no other arguments, the outstanding claim rejections under 35 U.S.C. 102 and 35 U.S.C. 103 over Nash are maintained herein.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 10, 21, 22, 24, 34-36 and 38-41 rejected under 35 U.S.C. 102(b) as being anticipated by Nash et al (U.S. Patent No. 6,007,563).

With respect to **claim 21**: Nash discloses a device for at least partially closing an opening in tissue in the form of an arterial puncture. The device comprises an elongate body in the collective form of introducer sheath 28 and closure device 20 comprising a first lumen 102 of closure device 20 having a first distal opening proximal artery plug 32 and a second lumen defined by the sheath 28 having a second distal opening at the end of the lumen closer to the artery. (Figs. 15,17,24, Col. 5, lines 17-22) The lumens are arranged so that a longitudinal space is defined between the first and second distal openings (Fig. 17) A first connector in the form of luer fittings 110 and 112 is adapted to provide access to the first lumen 102 and a second connector indicated generally at 28E in Fig. 13 is adapted to provide access to the second lumen defined by the sheath 28. (Col. 7, lines 41-52, Col. 8, lines 1-6) The device comprises a wound cover member in the form of anchor member 32 releasably connected to the elongate body at the first distal opening of first lumen 102. As to the limitation “wherein the first distal opening is permanently maintained at a position distal of the second distal opening”, the word “permanently” is not found anywhere in applicant’s disclosure. Therefore, although the claims are interpreted in light of the specification, limitations from the specification are not read

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into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Thus the claim is given its broadest reasonable interpretation. Once the closure device is fixed in place in the sheath, the first distal opening of lumen 102 is considered herein to be permanently maintained at a position distal of the second distal opening of the second/sheath lumen during the course of placement of the wound closure member 32. The first and second lumens do not communicate with one another and the wound cover member 32 and the elongate body are configured so that when the wound cover member 32 is released from the first distal opening of first lumen 102 of the elongate body at or adjacent an opening in tissue, i.e. the puncture, the wound cover member 32 is wholly disconnected from the device. (Fig. 38, Col. 5, lines 17-22)

With respect to **claim 10**: The elongate body disclosed by Nash has a first portion 20 comprising the first lumen 102 and a second portion 28 comprising the second lumen, and the first and second portions are rigidly connected to one another by engagement of lumen 104 with introducer valve 28A so as to always move as a single elongate unit. (Col. 7, lines 42-48)

With respect to **claim 22**: The second/sheath lumen disclosed by Nash is configured to communicate a flowing fluid therethrough, namely blood via window 204. (Col. 9, lines 12-20)

With respect to **claim 24**: The device disclosed by Nash additionally comprises a release rod in the form of tamping member 130 having tag 138 sized and configured to slide through the first lumen 102 and into contact with the wound cover member 32. (Col. 8, lines 30-48)

With respect to **claim 34**: The device disclosed by Nash additionally comprises a release rod in the form of tamping member 130 having tag 138, wherein the first lumen 102 is adapted to

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slidably receive the release rod 130,138 therein via application of tension on suture 34 and tag 138 via torsion spring 142 to pull tamping member 130. (Col. 8, lines 36-48)

With respect to **claim 35**: The wound cover member 32 has a maximum diameter that is greater than a diameter of the second/sheath lumen distal opening. (Figs. 19,22)

With respect to **claim 36**: Nash discloses that the first lumen comprises luer fittings 110,112 which is by its nature fully capable and adapted to connect to a vacuum source such as a syringe having a mating luer component when the piston is pulled back. (Col. 8, lines 1-8)

With respect to **claim 38**: The second connector 28D is disclosed by Nash is adapted to selectively connect to a source of vacuum so as to draw a vacuum through the second lumen. (Col. 9, lines 23-31)

With respect to **claim 39**: The second connector is a sideport 28D and is considered herein to be adapted to selectively connect to a source of irrigation fluid, since it contains a stopcock valve which is effective to regulate blood flow in and out of the second connector, wherein blood is also a fluid. (Col. 9, lines 17-21)

With respect to **claim 40**: The second connector 28D is considered herein to be adapted to selectively connect to a source of flowable adhesive so that flowable adhesive may flow through the second lumen and out the second distal opening since it contains a stopcock valve which is effective to regulate fluid flow (i.e. blood flow) in and out of the second connector. (Col. 9, lines

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17-21)

With respect to **claim 41**: The second connector 28D defines a second connector lumen, and an axis of the second connector lumen is disposed in a direction generally transverse to an axis of the second lumen. (Fig. 12)

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nash et al (U.S. Patent No. 6,007,563).

With respect to **claim 37**: Nash discloses that the wound closure member is held onto the first distal opening by a suture 34 and sealing plug 30 in a pulley arrangement. (Col. 5, lines 10-16) Thus Nash does not disclose that the wound closure member is held onto the first lumen distal opening by the vacuum. However, a vacuum would simply be an alternate means of applying force to the member to hold it onto the first distal member that would function in a mechanically identical manner to the pulley arrangement of the sealing plug 30, wound cover member 32 and suture 34 when a pulling force is applied. Therefore it would be obvious to one of ordinary skill

in the art to modify the device of Nash such that the suture is replaced by vacuum through the first lumen as a means for holding the wound closure member onto the first distal opening.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Examiner, Art Unit 3761